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An Introductory Overview

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## **NANOTECHNOLOGY WITHIN THE LEGAL AND REGULATORY FRAMEWORK: AN INTRODUCTORY OVERVIEW**

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**Nanotechnology**, often referred to as the next industrial revolution after the internet, is an interdisciplinary study and the wave of the future. It is the science of manipulating technology at an atomic and molecular scale and is no longer an issue for scientists only. It has limitless potential and can be used in most areas of human need. Based on very optimistic results in many scientific researches around the world, it can easily be inferred that its limitless promises will bring epoch making changes in the world very soon. There are already over 2,000 consumer products in the market which are developed containing nanoparticle and that use **nanotechnology**. However, there are also concerns as there are many who consider

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nanoparticles as the next asbestos and are reluctant to welcome **nanotechnology** with an open mind. This is a matter of great concern that the global community is still in search of a consensus on legal and regulatory frameworks to govern it. As of now, there are many areas ie product safety, privacy and civil liberties, occupational health and safety ('OH&S'), intellectual property ('IP'), international law, environmental law, law of insurance, law of customs, consumer protection and waste management which are directly related to **nanotechnology** research, development and commercialisation, and the law must intervene in these areas. While the benefits that can be achieved by using **nanotechnology** are whole-heartedly welcomed and appreciated, this paper aims at introducing the legal aspects of **nanotechnology** with an appeal that the development of **nanotechnology** should be regulated properly and the scientist must not be given a blank cheque in their hands to make experiments that may create adverse effects. The mistakes which halted the introduction and commercialisation of genetically modified food or nuclear energy should not be repeated and the application of **nanotechnology** should be encouraged within the approved legal framework.

## INTRODUCTION

**Nanotechnology**, the next industrial revolution after the internet, has turned to be a darling child for people of all subjects, and different researchers and bodies have been sharing this term with different adjectives.

**Nanotechnology**, which can be applied in a vast array of disciplines, is very attractive as a generic technology (diversified applications as information and communication technology ('ICT')), or an enabling technology (adding new functions to existing products), and has disruptive potentiality (can displace existing products or obliterate a particular type of product in the market).<sup>1</sup> It is a transformative technology and can be compared with the steam engine in the 18th century and the electricity in the 20th century in terms of effect.<sup>2</sup> **Nanotechnology** is a disruptive technology ie a technology which is very cheap, user friendly and can be used for multi-purposes. Again, it is considered a 'general purpose' technology whereby its advanced form will have significant impact on almost all industries and all areas of knowledge.

**Nanotechnology** is no more *terra incognita*, an issue of science fiction or concern of scientists and engineers only; rather it has turned to be an inter-

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disciplinary study. Much of which were previously found in science fictions are now part of reality. However, **nanotechnology** is still at an early phase of development, and is sometimes compared in the literature to information technology in the 1960s and biotechnology in the 1980s.

Sharing the findings of Salamanca-Buentello *et al*, the United Nations Educational, Scientific and Cultural Organization ('UNESCO') traced top ten applications of **nanotechnology** within the United Nations ('UN') Millennium Development Goals ('MDGs'), which are: (a) energy storage, productions and conversion; (b) agricultural productivity enhancement; (c) water treatment and remediation; (d) disease diagnosis and screening; (e) drug delivery systems; (f) food processing and storage; (g) air pollution and remediation; (h) construction; (i) health monitoring; and (j) vector and pest detection and control.<sup>3</sup> The UN is convinced that **nanotechnology** has the prospect to improve the lives of five billion people in the developing countries. The International Labour Organisation ('ILO') predicts that by the year 2020, almost 20% of products from all over the world will be developed using **nanotechnology**.<sup>4</sup>

With all these promises, there are many concerns on the safe application of this technology. Hundreds of papers have already been written on health and environment concerns and safety issues regarding this technology. Apart from the laboratory researches, there are many researches which are conducted on animals and the adverse effects of this technology were noticed. Furthermore, in many of the researches,

concerns were expressed that the people who are directly in contact with the technology ie the researchers and the workers are in real danger. Therefore, the law should intervene to regulate this technology. Previously, it has been seen that genetically modified foods and nuclear energy were introduced with unlimited prospects, but was not successful due to many factors. Due to numerous prospects, it is whole heartedly desired that the **nanotechnology** innovation should be continuous, but within the regulatory framework.

This paper aims at sharing an introductory overview on **nanotechnology** and its legal and regulatory aspects. To this end, the paper is divided into four main parts, apart from introduction and conclusion. Part 2 analyses different concepts relating to the study of **nanotechnology**, Part 3 shares some concerns

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relating to **nanotechnology** research and development ('R&D'), Part 4 will shed focus on the legal aspects of **nanotechnology** and regulatory developments around the world and finally, some suggestions will be shared in Part 5.

## BACKGROUND DISCUSSION

### Conceptual analysis

There are many misconceptions on the different terms used in the study of **nanotechnology**, and in many cases, some of the words used like 'nanoparticles', 'nanomaterials', and '**nanotechnology**' are used interchangeably. Therefore, it is important to understand the meaning of some of the important terms in this area of study, which will be discussed below.

#### (a) Nano

The word 'Nano' derives from the Greek word 'Nanos' meaning 'dwarf'. It is used to refer to a unit of measurement like millimetre, centimetre, metre, kilometre, feet, yard, bite, byte, kilobyte, megabyte, gigabyte, etc. According to the International System of Units (SI) a 'nanometer' (nm) is one billionth of a meter or a millionth of a millimetre. To share some examples, a sheet of paper is about 100,000nm thick, there are 25,400,000nm in one inch and a strand of human hair is roughly 75,000nm across.

Now, a question may be raised on how this unit of measurement can be an issue in legal studies. The answer is yet to be found, and is still in its research stage before a final decision is made. Suffice to share here that at the nanoscale, the characteristics of the material can be significantly changed, particularly under 10-20nm, because of properties such as the dominance of quantum effects, confinement effects, molecular recognition, and an increase in relative surface area. Downsized material structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties, as well as chemical reactivity leading to surprising and unpredicted, or unpredictable, effects. In essence, nanodevices exist in a unique realm, where the properties of matter are governed by a complex combination of classic physics and quantum mechanics. At the nanometer scale manufacturing capabilities (including self-assembly, templating, stamping, and fragmentation) are broad and can lead to numerous efficient outcomes.<sup>5</sup>

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#### (b) Nanotechnology

Nobel Laureate Richard Smalley defined **nanotechnology** as the art and science of building stuff that does stuff at the nanometer scale.<sup>6</sup> Different organisations, persons and countries define '**nanotechnology**' from different perspectives. A close analysis of these definitions will reveal that most of them are derived from the definition suggested by the United States of America's National **Nanotechnology** Initiative ('NNI'), is as follows.

- (a) Research and technology development at the atomic, molecular, or macro-molecular levels, in the length scale of approximately 1 to 100-nm range.
- (b) Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size.
- (c) Ability to control or manipulate on the atomic scale.<sup>7</sup>

In the absence of any authoritative definitions, 18 definitions of **nanotechnology** given by different people were identified. It was concluded that the following five characteristics are crucial:

- (1) Size: from around 100nm down to less than 0.1nm.
- (2) Range of technologies: imaging, measuring, modelling and manipulating the matter.
- (3) Multi-disciplinarity: including for instance, physical, chemical and biological, with each being purposefully 'engineered'.
- (4) Size dependent novel properties and functions.
- (5) The control and purposeful manipulation of matter at the atomic scale.<sup>8</sup>

### **(c) Nanomaterial**

In simple words, the term 'nanomaterials' is used to refer to a material which is developed by using nanoparticle. The European Commission in its report on *Considerations on a Definition of Nanomaterial for Regulatory Purposes* considered and shared all the definitions given by different international

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organisations such as the Organisation for Economic Co-operation and Development ('OECD'), the European Union ('EU') Scientific Committee on Emerging and Newly Identified Health Risks, the EU Cosmetic Products Regulation, etc and definitions which are available in municipal legislation of different countries including Australia, Canada, Denmark, the United Kingdom (UK) and the United States of America (USA). The EC has defined nanomaterials as '*materials with internal structures and/or external dimensions within the size range measured in nanometers (nm) where 100 nm is frequently used as a delimiting size between the nanoscale and the micro and macroscopic scales*'.<sup>9</sup> Though the attempt of the EU has been welcomed, this definition is not free from criticisms. The Brussels based European Chemical Industry Council, Cefic found that the definition is '*too broad in scope*' which will be difficult to be integrated in the existing legislation in a meaningful way as this will add unnecessary burden for companies, leading to added costs and less efficient use of resources and some decades -- old substances eg mineral pigments used in paints and other everyday products will be termed as nanomaterials.<sup>10</sup> This definition will be reviewed in December 2014 by the EC.<sup>11</sup>

From a regulatory point of view, the definition is extremely important as unless one thing cannot be defined properly, legal sanctions and attributes cannot be attached to it. The issue of definition deserves further attention because of the unanticipated environmental and health hazards which may occur from nanoparticles. Realising the importance of a definition, the European Parliament emphasised on introducing a comprehensive science-based definition of nanomaterials. The definition is further crucial to assess the level of liability of different people engaged in **nanotechnology** research and business. However, one of the leading experts in advocating the definition of nano, Andrew Maynard realised that for nanomaterials, the definition of 'one size fit for all' may not be suitable and therefore, it is better to define nanomaterials, case-by-case.<sup>12</sup>

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### **(d) Nanoparticle**

Nanoparticle, a microscopic particle or powder with at least one dimension of less than 100nm, is considered as a miracle or magic fibre. There are three types of nanoparticles: 'engineered' nanoparticles (such as buckyballs and gold nanoshells), 'incidental' nanoparticles (such as those found in welding fumes, cooking and diesel exhaust), and 'naturally occurring' nanoparticles (salt spray from the ocean, or forest-fire combustion). Such 'naturally occurring' nanoparticles which are ubiquitous in nature produced by fire, volcanic eruption, etc can easily be well refined by the defensive mechanism of the human body. However, the situation can be changed with the changing of natural nanoparticles into deliberately created engineered nanoparticles. Only 'engineered' nanoparticles constitute an entirely new class of particles and, to date, buckyballs are the only engineered nanoparticles that have been seriously studied. As for the 'incidental' nanoparticles (often referred to as 'ultrafine particulate matter'), these have clearly been more extensively studied eg auto exhaust. The handful of studies on the toxicity of fullerenes so far suggest that they are

indeed hazardous -- but also that they can be engineered to be less so, in particular by conjugating other chemicals to the surface of buckyballs, thus changing their chemical properties.<sup>13</sup> Nanoparticles can take different shapes -- cylindrical, discoidal, spherical, tabular, ellisodial, equant or irregular. Based on the published scientific literature on this area, it has been reported that there are around 5000 nanoparticles (ref) and many more are still in the pipeline as scientists have been researching to introduce more variety of nanoparticles.

### **Emergence of nanotechnology**

Ideas or techniques of using nano level particles are not a new thing. The use of nanoparticles like silver in its pure form was used in ancient Greece; nanoparticles in ceramics were used in ancient Rome,<sup>14</sup> China and India. It is surprising to note that nanoparticles have existed on the planet for centuries ie smoke particles and viruses and there are many examples of structures in the nature that exist with nanometer dimensions ie DNA, proteins, cells, etc.<sup>15</sup> There are also some research where scholars have traced some religious roots of

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**nanotechnology.**<sup>16</sup> However, it is pertinent to mention here that the nanoparticles which are ubiquitous in nature are not the subject matter in the study of **nanotechnology** 'and only the deliberately modified engineered or manmade nanoparticles, where different attributes can be added, are considered in the study'.

The history of modern **nanotechnology** started with the ground breaking lecture of the founding genius and Noble laureate Richard Feynman titled 'There's Plenty of Room at the Bottom'<sup>17</sup> at the meeting of the American Physical Society at the California Institute of Technology (CalTech) on 29 December 1959. Richard Feynman shared the principle of the possibility of maneuvering things atom by atom, though he admitted that he had yet to try it. In 1974, Japanese Professor Norio Taniguchi of Tokyo Science University first coined the term '**nanotechnology**'. The invention of the scanning tunneling microscope ('STM') developed by the International Business Machines ('IBM') researchers in November 1989 to make the logo of the company by assembling atom after atom added new dimension in the history of **nanotechnology** research.<sup>18</sup> After the invention of the STM, almost every day, new materials are developed and new consumer products are entering into the market which are cheaper, stronger, reliable, durable and with other user-friendly features.

### **Prospects of nanotechnology and some statistical predications**

With its limitless potential, it is apparent that **nanotechnology** has turned to be the business of people of all strata. The findings of different research are as diversified as the potential of **nanotechnology**. In an article in Nature, it was found that between August 2008 to July 2009, there were more than 91,500 publications on **nanotechnology**.<sup>19</sup> More than \$32 billion in products containing nanomaterials were sold globally in 2005. The Lux Research, Inc reported in 2009

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that nanotechnologies were used in goods and products and the value is \$224 billion.<sup>20</sup> Canada based Electronics.ca Publications estimated that the global market for **nanotechnology** in 2010 was \$15.7 billion and projected that the market will be of \$27 billion in 2015. In 2000, the US National Science Foundation ('NSF') estimated that the global marketplace for goods and services using nanotechnologies will grow to \$1 trillion by 2015,<sup>21</sup> whereas the German Ministry of Education and Research is convinced that the amount will be \$3 trillion.

BCC Research Market estimated the global market for **nanotechnology** products at about \$15.7 billion in 2010, growing to approximately \$26.7 billion by 2015, a compound annual growth rate of 11.1% from 2010 through 2015.<sup>22</sup> Another leading market research organisation, Cientifica, reported in 2011 that the different governments around the world are currently spending \$10 billion per year with a growth rate of 20% over the next three years. In the USA, after launching the world's first national **nanotechnology** program, the government invested a total of \$15.6 billion in between 2001-2012 and the President requested to allocate \$1.766 billion (\$70 million more which is 4.1% higher than the previous year) for the year 2013 for the NNI.<sup>23</sup>

### **HOW NANOPARTICLES CAN AFFECT US**

It is now accepted that all kinds of technology has some adverse effect on human health and environment and as an emerging technology, **nanotechnology** is no different. Even though every report on **nanotechnology** expresses concerns regarding health and environmental impacts of nanomaterials, till date, all the experiments with the nanomaterials and its adverse effects are mainly laboratory based and the long term effects of the nanoparticles have not been tested. Therefore, one single accident may significantly shake the confidence of the consumers. For example, the Japanese people were not against the use of nuclear energy, but the recent Fukushima Nuclear Power Plant Disaster in 2011 due to the tsunami makes them afraid of the nuclear power. Similarly was the case with asbestos and tobacco. Asbestos, in ancient Rome, was treated as unpolluted and had been used at unlimited

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scale from and after the industrial revolution. However, after the first case was detected in 1924, the Asbestos Industry Regulations 1931 was enacted in the UK. Now, because of its adverse health impacts, asbestos is statutorily banned in many countries around world. Similarly, tobacco was initially promoted as cash crop and was treated as medicine for all diseases. It was only in the mid-1960s, when the Chief Surgeon of the USA wrote an article indicating that tobacco may cause cancer. From then on, people have started a war against tobacco and it is now statutory prohibited in certain circumstances. This is the main concern with **nanotechnology**. Nanoparticles can enter the human body through the lungs, the intestinal tract, and skin,<sup>24</sup> and are likely to be a health issue, although the extent of the effects on health is inconclusive. Chiu-Wing Lam of the National Aeronautics and Space Administration (NASA)'s Johnson Space Center conducted a study and found that carbon nanotubes, when directly injected into the lungs of mice, could damage lung tissue.<sup>25</sup> The School of Public Health of the Harvard University confirms that 'there is mounting evidence that engineered nanoparticle (ENPs) exposure can lead to DNA damage that ultimately contributes to cytotoxicity and mutations that drive cancer.'<sup>26</sup>

From the inventory of Project of Emerging **Nanotechnology** ('PEN'),<sup>27</sup> it is revealed that out of around 2000 consumer products, 354 products are open to dermal exposure, 173 are able to be ingested and 171 can be inhaled. However, even though these products can be exposed to human health, their adverse health effects are not tested and therefore, there is no evidence that these products are dangerous.

Simultaneously, it has not been proven on how the nanoparticles will react in the environment and how the biodiversity will be affected with the release of nanoparticles which are not sufficiently tested. In such circumstances, the Federal Environment Agency of Germany has advised consumers against the use of products containing nanomaterials. The Australian Workers' Union has expressed their concern on the use of nanoparticle by linking nanoparticle with asbestos and has advocated for proper regulation.

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## LEGAL AND REGULATORY ASPECTS OF **NANOTECHNOLOGY**

At the very outset of the discussion, it should be made clear that the study of **nanotechnology** law is primarily considered under the study of laws relating to chemicals, and not all of the nanomaterials reported in scientific journals (around 5000) are dangerous. Nanomaterials being nanoscale chemical have more or less similar features of chemicals with some unusual results. Similar to the notion that not all chemicals are harmful, nanomaterials are of no exception, although there are some nanomaterials which are used in a ubiquitous scale in consumer products that are highly predicted to be injurious. For such nanomaterials, law should immediately intervene.

However, since it has turned to be an interdisciplinary study, more issues than the chemicals are involved here. The global community is still unsure on whether the conventional legal provisions relating to chemicals and chemical management will be sufficient and applicable in the case of nanoparticle, or whether new law should be enacted.

This is also agreed upon by researchers and regulators that the legal and regulatory issues relating to nanomaterials can be best understood from its life cycle ie from laboratory to consumer products, to disposal in the environment. If we can analyse the life cycle of nanomaterials, it will be revealed that many areas of laws eg laws relating to occupational health, factory, chemical substance, hazardous substance, consumer, waste, environment (land, air and water), food and agriculture, fisheries, biodiversity, cosmetics, food



packaging and labelling, medical devices, intellectual property, insurance etc may be relevant in the discussion of different aspects of **nanotechnology**. Specific mention of the term with 'nano' cannot be found as it is still premature, but there should have provisions that can be interpreted. For example, the laws relating to occupational health are enacted, inter alia, to secure the safety, health and welfare of persons at work, for protecting others against risks to safety or health in connection with the activities of persons at work.<sup>28</sup> Such provisions are very broad and can be interpreted to include that the risk and safety issues relating to nanomaterials can be regulated under this law. Similarly, for example, the Malaysian Food Act 1983 (Act 281) was enacted to protect the public against health hazards in the preparation, sale and use of

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food. Therefore, any kind of nanomaterial with an intention to use in food,<sup>29</sup> which may be found to be injurious to human health, can be considered through the provisions of this law. This is similar with other areas of law. The issue of concern however, is that having the provision and favourable interpretation of the law is not sufficient unless it cannot be implemented to cover emerging technology eg **nanotechnology**. Therefore, this is crucial to consider the adequacy of the existing legal framework whether such legal framework is enough to regulate the R&D of **nanotechnology**.

### **Nanotechnology and different regulatory models**

There are many international organisations that have been working to develop some regulatory framework to handle nanomaterials. For example, international organisations like the Food and Agricultural Organisation ('FAO') and the World Health Organisation ('WHO') have been working on nanotechnologies in food and agriculture.

There are some regulatory models which are practiced around the world. Though there are statutory laws on **nanotechnology** in the USA ie the 21st Century **Nanotechnology** Research and Development Act of 2003 and in South Korea ie the **Nanotechnology** Promotion Act 2009 (Act No 8852), in most of the cases, the **nanotechnology** R&D is carried out through different government strategy papers, roadmaps, statements, policies, etc. The laws of the USA and South Korea do not contain any legal provisions, rather the laws contain provisions relating to **nanotechnology** administration and development within the country.

In many cases, different governments around the world encourage voluntary regulation ieto take voluntary initiatives to minimise the adverse effects of nanomaterials. Besides, there are a number of guidelines used in different sectors relating to **nanotechnology** eg in different laboratories and universities, there are some guidelines that handle nanoparticles.

Chemical organisations are expected to provide the Material Safety Data Sheet ('MSDS') to give an indication of the possible adverse effects of the

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chemical to the human health and environment. It is interesting to note that the MSDS has evidentiary value in the courts of law. For example, the Kuala Lumpur High Court in the case of *Ing Hua Fu Marine Line Sdn Bhd v Vitachem (M) Sdn Bhd & Anor*[2013] 9 MLJ 825, recognised the MSDS in relation to a chemical explosion in Port Klang by the vessel Ing Hua Fu, resulting in damage of the vessel and the cargo. The court found that in order to comprehend the nature and characteristics of the chemicals it is necessary to study the MSDS for each chemical. The safety data sheet which draws reference from UN, 2011, Globally Harmonized System of Classification and labelling of Chemicals, is a means of communication of information about a substance or mixture for use in the workplace for the purposes of establishing a chemical control regulatory framework. It is a source of information on the hazards a substance poses and 'provides guidance on safety precautions'. The court further held that the MSDS is issued by a manufacturer of a product and provides an important source of information for the transportation sector and emergency responses. To add to this, in the earlier case of *Tropical Network Sdn Bhd v Geo-Chem Inspection (M) Sdn Bhd (FIMA Bulking Services Bhd, third party)*[2011] 8 MLJ 359, the High Court (Johor Bahru), in a different context referred to the MSDS.

In order to regulate nanomaterials, some countries start with registration of nanomaterials. It is anticipated that once the registration is complete, it will be easier to regulate it. However, an important aspect of registration is on how the regulators will handle the situation when the companies register their substances with the chemical regulatory bodies and then if the companies change the size of the substance into

nano-scale, which the regulators are now unable to monitor. To add to this, in most of the cases, R&D issues and institutions are exempted from the regulation under municipal legislation and if that is the case of **nanotechnology**, this may create some dangerous consequences.

The OECD suggested that **nanotechnology** can be regulated the same way biotechnology has been being regulated. Furthermore, as there are significant resemblances between asbestos and **nanotechnology**, the way governments around the world have handled asbestos can also be applied in regulating **nanotechnology**.

Besides, the experts in the area who opine that the existing regulatory set up is sufficient to handle nanomaterials argue that some of the tort law principles eg precautionary principle, polluter pay principle, strict liability etc can also be of great use in this regard.

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### **Steps to regulate nanotechnology**

Even though there are a number of steps which are suggested by researchers from different disciplines to be taken to regulate **nanotechnology**, there is no international consensus on this issue. However, an analysis on the practice from around the world provides some clue on how regulatory initiatives can be taken in this regard.

The EC's Joint Research Committee identified that the main scientific challenges of implementation of legislation are the definition of nanomaterials, safety assessment (methodology for risk assessment), control of products containing nano materials (market regarding labelling and traceability, analytical methods, sampling, etc), and quality assurance tools (reference methods and materials).<sup>30</sup>

The issue of definition is crucial in regulating nanomaterials. Once the definition is settled, then the issue of registration will arise ie the registration of different types and amount of nanomaterials, adverse effects, risk assessment and exposure assessment of such nanomaterials etc.

The risk and safety assessment of nanomaterials are also important. Different organisations have been working to settle effective risk and safety assessment. One of the main challenges in this regard is that at the nanoscale, especially between 1-20nm, different nanomaterials behave differently. Therefore, when the International Center for Technology Assessment and a coalition of consumer, health and environmental groups filed a legal petition against the Environment Protection Agency of the USA to ban more than 200 consumer products using nano-silver, the court favoured case-by-case assessment.

The municipal legislation should then be assessed to ensure the adequacy of different laws eg laws relating to chemical substance, occupational health and safety, environmental legislation, waste management, product liability, consumer protection, etc.

### **Nanotechnology and legal framework in the world**

There is no comprehensive legislation in any country in the world to deal with nanoscale materials. Countries have been working to reach to a legal solution to

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deal with **nanotechnology**. However, there are already sectoral legislation on occupational health, environment, product labelling or cosmetic legislation, product liability, healthcare or chemical, etc in most countries. Due to scientific uncertainties, the countries are reluctant to enact laws and in the absence of comprehensive laws, these sectoral legislations may assist the countries.

One of the main reasons behind non-legislation is that there is a significant knowledge gap between the health and environmental effect of **nanotechnology**. Since all the tests and experiments are laboratory based, people are not sure about the adverse effects of **nanotechnology**. An incident occurred in China in a paint factory where seven workers while dealing with nanoparticles, were affected by the nanoparticles though it is not sure whether the nanoparticles were responsible for the injury. Even though this is not confirmed, it has ignited serious debate on regulation and safe handling of nanomaterials. In this context, let



us consider the legal framework relating to **nanotechnology** around the world in a brief manner.

In 2003, the USA enacted the 21st Century **Nanotechnology** Research and Development Act of 2003 to establish a National **Nanotechnology** Program ('NNP'), for funding for **nanotechnology** R&D over 4 years, starting in Fiscal Year 2005. It provided authorisations under s 6 of the Act for a subset of the NNI, one of the President's highest multi-agency R&D priorities, namely the NSF, Department of Energy ('DOE'), NASA, National Institute of Standards and Technology ('NIST'), and the Environmental Protection Agency ('EPA'). NNI is now a collaborative, multi-agency, cross-cut programme among 26 Federal entities with a range of research, industry, trade, educational and regulatory roles and responsibilities. This Act contains basically administrative provisions and there is nothing with **nanotechnology** and its adverse effects. However, the Toxic Substances Control Act; Occupational Safety and Health Act; Food, Drug and Cosmetic Act; and the other major environmental laws (Clean Air Act, Clean Water Act and Resource Conservation and Recovery Act) provide some legal basis for reviewing and regulating nanomaterials.

The Toxic Substances Control Act ('TSCA') 1976 allows the EPA of the USA to regulate new commercial chemicals before they enter the market, to regulate existing chemicals (1976) when they pose an unreasonable risk to health or to the environment, and to regulate their distribution and use.

In the UK, for example, the Health and Safety at Work etc Act (1974) sets out the responsibilities for health and safety that employers have towards employees and members of the public, and employees to themselves and to

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each other. As nanomaterials are primarily handled by the workers and researchers, such laws relating to health and safety may serve the present need.

There are a few government agencies in charge of nanomaterials in Australia and the list includes the National Industrial Chemicals Notification and Assessment Scheme ('NICNAS'), the Therapeutics Goods Administration ('TGA'), the Australian Pesticides and Veterinary Medicines Authority ('APVMA'), the Food Standards Australia New Zealand ('FSANZ') and the Australian Competition and Consumer Commission ('ACCC'). Even with all these agencies, it can safely be said that Australia's present regulatory set up does not completely regulate nanomaterials. Researchers have found that though there is no immediate need for major changes to the regulatory regimes, there are many areas of Australian regulatory regimes which, potentially, will need amending. This will be a long term effort across multiple regulators and regulatory agencies as nanoproductions arise and as new knowledge on hazards, exposure and monitoring tools become available.<sup>31</sup>

Colin Gavaghan and Jennifer Moore reviewed the adequacy of New Zealand's regulatory systems across the workplace and food safety, environmental protection and for consumer products, to manage the possible impacts of manufactured nanomaterials.<sup>32</sup> They concluded that none of the areas of the New Zealand regulatory system require wholesale changes in order to be applicable to nanomaterials and the regulatory mechanisms applicable to conventional products will, in broad terms, apply to nanomaterials. Nonetheless, they identified a number of possible regulatory gaps or weaknesses that are more specific to products containing manufactured nanomaterials (mNMs) and appear to occur at different levels: respectively, at the level of legislation, at the level of regulatory policy and at the level of compliance and enforcement.<sup>33</sup>

Among the Asian countries, countries like Japan, China, India and so on adopted some guidelines focusing on different aspects of nanomaterials. Countries like Iran, Taiwan and Thailand have introduced voluntary Nano Mark system. Iran as a result of introducing nano marking system also declared some incentives for the companies that will be willing to use nano marking in

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their goods. Such marking system corresponds to the European Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH'), Regulation which advocates for mandatory labelling.

### **Nanotechnology regulation and recent developments**

There has been a series of debates globally on the appropriate framework to regulate **nanotechnology**. The

role of different non-governmental organisations ('NGOs') like Friends of the Earth, Greenpeace etc and different reports published by these NGOs have added extra fuel in the debate. In the USA, the legal battle in the court of law formally started with the petition of the National Titanium Dioxide Association against the Environment Protection Agency in 2006. Though the petition was not ultimately successful, it can be anticipated that it will open the floodgate of a number of legislative movements around the world. In November 2013, the 9th Circuit Court of the USA declared against the use of nanosilver in baby blankets.

There are some significant developments to regulate **nanotechnology** in Europe too. Nanomaterials are claimed to be regulated within the authority of the European Commission through the Regulation (REACH), which entered into force on 1 June 2007. In February 2012, the final decree of the French Ministry for Ecology, Sustainable Development, Transportation and Housing introduced the first mandatory reporting scheme for nanomaterials in Europe. The decree, which has been in operation from January 2013, was adopted to have a better understanding of nanomaterials and their use, to enable better traceability, to have a better knowledge of the market and volume of nanomaterials involved and to collect available information on toxicology and ecotoxicology of nanomaterials. Under the decree, the importers, producers, distributors of nanomaterials, as well as 'professional users' and research laboratories located in France that manufacture, import or distribute nanomaterials in quantities of  $\geq 100\text{g}$  must submit a declaration on 1 May of every year containing information on the quantity and use to the Minister of the Environment. The decree entails the French National Agency for Food Safety, Environment and Labour (ANSES) for management of data collected. Belgium and Denmark are in the process of following the instances of France. Among the Latin American countries, in Brazil, some steps have been taken, though unsuccessful till date, towards regulating nanomaterials through the product labelling law.

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## SUGGESTIONS

There are many reports published by some government authorities worldwide claiming that the nanoparticles and nanomaterials were not found to be injurious to human health and the environment. However, with the exception of some NGOs, consumers remain mostly silent due to the fact that no serious harm is caused. The whole scenario may be changed with the occurrence of one single accident.

To date, most of the research are laboratory based and the actual effect of nanoparticles and nanomaterials in the environment are yet to be conclusively confirmed. The regulators have a serious role to play to protect the citizens and cannot remain relaxed until an accident occurs. Therefore, there is no alternative to conduct more research.

The citizens as the main stakeholder should be involved in the whole process and be given the scope to decide. Since government projects on **nanotechnology** are run on the tax payers' money, the regulators should organise promotional and awareness activities so that the citizens are provided with sufficient information to decide on whether they should accept or reject nano-enabled products.

Considering the huge amount of investment required to assess the risks and safety of all consumer products developed through nanomaterials, collaboration among the countries are very important.

Some guidelines are to be framed immediately based on the existing research findings. A positive movement of government as the regulator, scientists as communicator and business entities as the primary funding body is desired. Such a movement will be beneficial for all, as regulators have the statutory and moral responsibility to protect the citizens from all kinds of dangers, scientific communities have the moral obligation to use the research finding for mankind, and business communities must carefully invest to avoid possible risks and accidents.

## CONCLUSION

Human beings should be in the center of all development activities. The future of this planet is greatly dependent on how we will use its resources. **Nanotechnology** has virtually limitless potential with some challenges and if these challenges can be managed and handled smartly, **nanotechnology** will truly be a

blessing for the coming world. Engineered or manufactured nanomaterials are referred to as the top emerging workplace risk by the EU's

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Agency for Health and Safety at Work and have repeatedly been rated as a top global technology risk in the annual World Economic Forum reviews since 2006. Therefore, a coordinated effort from all, be it corporate managers, shareholders, stakeholders, regulators, policy makers, analysts and consumers is the demand of the time since all have common but differentiated responsibilities to this end. In this regard, the regulators should take the lead based on the results and findings of existing research. **Nanotechnology** can be termed as the present day's Aladdin's Magic Lamp and therefore, the growth and development of this area of knowledge within clear legal and regulatory framework should be encouraged.

- 1 See Shilpa, S B, & Bhati, M (2012), *China and India: The Two New Players in the Nanotechnology Race*, Scientometrics (10.1007/s11192-012-0651-7), doi: 10.1007/s11192-012-0651-7.
- 2 See Hassan, M H A (2005), *Small Things and Big Changes in the Developing World*, Science 309 (5731), 65-66. doi: DOI: 10.1126/science.1111138.
- 3 See Salamanca-Buentello, F, Persad, D L, Martin, D K, Daar, A S, & Singer, P A (2005).
- 4 **Nanotechnology** and the developing world. PLoS Medicine, 2(5), e97 at [http://www.ilo.org/wcmsp5/groups/public/---ed\\_protect/---protrav/---safework/documents/publication/wcms\\_123653.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---safework/documents/publication/wcms_123653.pdf).
- 5 See Renn, O & Roco, M C (2006), *Nanotechnology and the need for risk governance*, Journal of Nanoparticle Research, 8(2), 153-191.
- 6 See Linkov, I, & Steevens, J (2009), *Nanomaterials: risks and benefits*: Springer.
- 7 See Mongillo, J F (2009), *Nanotechnology 101*, New Delhi: Pentagon Press.
- 8 See Hodge, G A, Bowman, D, & Ludlow, K (2007), *New global frontiers in regulation: The age of nanotechnology*. Edward Elgar Publishing.
- 9 See L'Åvestam, G, Rauscher, H, Roebben, G, KlÄttgen, B S, Gibson, N, Putaud, J-P, & Stamm, H (2010), Considerations on a definition of nanomaterial for regulatory purposes. Joint Research Centre (JRC) Reference Reports, 80004-80001.
- 10 See <http://www.cefic.org/PressReleases/Press%20statement%20nano%20definition.FINAL.pdf>.
- 11 See article 2 of the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Second Regulatory Review on Nanomaterials, 2012.
- 12 See Maynard, A D (2011), Don't define nanomaterials. [10.1038/475031a]. Nature, 475(7354), 31-31.
- 13 See Bhattacharya, S, & Bhati, M (2012), *China and India: The two new players in the nanotechnology race*, Scientometrics, 93(1), 59-87.
- 14 See, **Nanotechnology** is ancient history, the Guardian at <http://www.theguardian.com/nanotechnology-world/nanotechnology-is-ancient-history>.
- 15 See Francisco PrietoGarcÄa, J P M, and Ana M BolarÄnMirÄ³, (2013), *Nanotechnology and environment: Safety and health in exposure to nanoparticles and ceramics*, Journal of Research in Environmental Science and Toxicology, 2, 17-35.
- 16 For example, the Holy al-Quran has specific reference of atom and anything smaller than atom in Surahs *al-Nisa'* (4): 40, *Yunus* (10): 61 and *Saba'* (34): 3, 22, *al-Zalzalah* (99): 6-8. The word 'zarrah' is used as synonyms of atom.
- 17 The transcript of the Lecture, which was published in the Journal of Microelectromechanical Systems, R Feynman, 'There's Plenty of Room at the Bottom' Vol 1, No 1, pp 60-66, March 1992, is available at [http://media.wiley.com/product\\_data/excerpt/53/07803108/0780310853.pdf](http://media.wiley.com/product_data/excerpt/53/07803108/0780310853.pdf).
- 18 It may be interesting to share here that on 30 April 2013, IBM developed a film titled 'A Boy and His Atom: The World's Smallest Movie'.
- 19 Shapira, P, & Wang, J (2010), Follow the money, [10.1038/468627a]. Nature, 468(7324), 627-628.

20 See Cassandra D Engeman, L B, Benjamin M Carr, Allison M Fish, John D Meyerhofer, Terre A Satterfield, Patricia A Holden, Barbara Herr Harthorn (2012), *Governance implications of nanomaterials companies' inconsistent risk perceptions and safety practices*, Journal of Nanoparticle Research, 14, 749 doi: 10.1007/s11051-012-0749-0.

21 See Mongillo, J F (2009), *Nanotechnology 101*, New Delhi: Pentagon Press.

22 See 2010 *Nanotechnology* Research Review, BCC Research, at <http://www.bccresearch.com/market-research/nanotechnology/2010-nanotechnology-review-nan047b.html>.

23 See JF Sargent Jr, Federal Research and Development Funding: FY2013, 2013 at <http://www.fas.org/sgp/crs/misc/R42410.pdf>.

24 See Khaled Radad, M A-S, Rudolf Moldzio, Wolf-Dieter Rausch (2012), Recent advances in benefits and hazards of engineered nanoparticles, *Environmental Toxicology and Pharmacology*, 34(3), 661-672 at <http://dx.doi.org/10.1016/j.etap.2012.07.011>

25 See Mongillo, J F (2009), *Nanotechnology 101*, New Delhi: Pentagon Press.

26 See Mongillo, <http://www.hsph.harvard.edu/nano/research/a-high-throughput-nanogeno-toxicity-assay/>.

27 See The Project on Emerging Nanotechnologies, developed by the Wilson Center and Virginia Tech at <http://www.nanotechproject.org/cpi/>.

28 See Preamble, the Occupational Health and Safety Act 1994 (Act 514) (Malaysia).

29 Many kinds of nanomaterials or ingredients at the nanoscale can be used in food and the food packaging industry. For an overview, please read, Institute of Medicine (US) Food Forum. *Nanotechnology in Food Products: Workshop Summary*. Washington (DC): National Academies Press (US); 2009 2, Application of *Nanotechnology* to Food Products at <http://www.ncbi.nlm.nih.gov/books/NBK32727/>.

30 See <http://www.euronanoforum2013.eu/wp-content/uploads/2013/07/K-Maruszewski-ENF2013.pdf>.

31 See Australian Office of *Nanotechnology*, National *Nanotechnology* Strategy (NNS) Annual Report 2007-08 at [http://www.innovation.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Documents/NNSAnnualReport\\_2007-08.pdf](http://www.innovation.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Documents/NNSAnnualReport_2007-08.pdf).

32 See Colin Gavaghan and Jennifer Moore, A Review of the Adequacy of New Zealand's Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials, 2011 at <http://www.msi.govt.nz/assets/MSI/Archive/Nanotechnology-review.pdf>.

33 *Ibid*.